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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,217	12/03/2003	Mark B. Chidlaw	PC9858A	4494

28523 7590 06/06/2008

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/727,217	CHIDLAW ET AL.	
	Examiner	Art Unit	
	S. Tran	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/06/08 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. US 5,612,059, in view of Natalie Gauld (Medicines and Food-A Patient's guide).

Cardinal discloses a controlled release device comprising an active core and one or more asymmetric membranes (abstract; column 10, lines 26-63; and claims). Asymmetric coating comprises cellulosic material including cellulose acetate (column 7, lines 45-67; and claims 19-28). Active comprises drugs (column 10, lines 18-25) such as prazosin, nifedipine, trimazosin, doxazosin, hydroxyzine, sertraline, dazmegrel, glipizide, and the like (column 1, lines 63 through column 2, lines 1-12). Cardinal further discloses controlled release of active substance is by diffusion and/or osmotic pumping (abstract; column 9, lines 20-65; and column 10, lines 52-57).

Cardinal does not expressly teach administering the dosage form to a use environment that comprises at least about 0.5% of dietary fat.

Gauld teaches common medicines taken with food include nifedipine, glipizide, minocycline, theophylline, itraconazole, augmentin (amoxicilline and clavulanic acid), erythromycin and the like (abstract; and pages 1-3). Thus, it would have been obvious to one of ordinary skill in the art to administer the dosage form of Cardinal in combination with food in view of the teachings of Gauld to obtain the claimed invention. This is because Gauld teaches drugs taken with food or immediately after meal to increase absorption into the body, because Gauld teaches drugs commonly taken with food include nifedipine, glipizide, minocycline, theophylline, itraconazole, augmentin (amoxicilline and clavulanic acid), erythromycin and the like (ID), because Cardinal teaches a dosage form suitable for a wide variety of drugs including drugs that are commonly known to be taken with food such as nifedipine, and glipizide (ID), and because Cardinal teaches the use environment includes gastrointestinal tract (column 1, lines 29-61).

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. US 5,612,059, in view of Natalie Gauld (Medicines and Food-A Patient's guide) and Faour et al. 6,004,582.

Cardinal is relied upon for the reason disclosed above. Cardinal does not teach the taste mask and the immediate release coatings.

Faour teaches a process for preparing an osmotic dosage form comprising an active core **(5)**, a semipermeable membrane **(4)**, a water-soluble polymer coat **(3)**, and an immediate release active agent-containing external coat **(2)** (column 4, lines 63 through column 6, lines 1-13; and Fig. 2). The claimed active agents can be found in columns 13-15). Faour further teaches the dosage form is suitable to deliver one or more active agents to an environment of use in a controlled manner (abstract; column 1, lines 4-22; and column 5, lines 1-3). Semipermeable membrane includes cellulose acetate and polyethylene glycol (column 4, lines 24-34; column 9, lines 1-27; and examples). Faour further teaches a taste masked finish coating **(8)** (column 17, lines 58-64; and examples). Thus, it would have been obvious to one of ordinary skill in the art to modify the osmotic device of Cardinal to include an immediate release and a taste mask release coatings in view of the teachings of Faour, because Faour teaches an improved osmotic device that overcomes many of the disadvantages inherent in related prior art devices (column 3, lines 29-39), because Faour teaches an osmotic device that provides a broader range of independent release profiles for one or more active agents (id), because Cardinal teaches a controlled release device suitable for a wide variety of active substances, and because Cardinal teaches the desirability of obtaining an osmotic device to control the release of one or more active substances into an environment of use (column 4, lines 18-26).

Claims 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al., in view of Gauld (Medicines and Food-A Patient's Guide) and Faour et al. 6,004,582, and FDA press release or Camden US 6,136,835.

Cardinal is relied upon for the reasons stated above. Cardinal does not expressly teach a dosage form with a written matter indication.

FDA press release teaches an improved package inserts that include boxed warning, indications and usage, and dosage and administration (page 2). FDA press release further teaches the improved package inserts provide safe an optimal use of drugs, which improves health outcomes for patients and more efficient delivery of healthcare (page 1).

Camden teaches a pharmaceutical composition comprising a container, a dosage form, and a printed instruction either as an inserts or as labels, indicating quantities of the components to be administered, and guideline for administration (column 20, lines 1-15).

Thus, it would have been obvious to one of ordinary skill in the art to prepare a dosage form that includes a written indication to provide guideline for administration, because it is required by the FDA, and because it is well known in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 03/06/08 have been fully considered but they are not persuasive.

Applicant argues that Cardinal does not teach a method comprising administering the controlled release composition to the use environment comprising at least about 0.5% dietary fat.

The 102(b) rejection has been withdrawn in view of applicant's Remarks. However, while Cardinal is silent to the teaching that the composition is administered to a use environment comprising dietary fat, Cardinal does not preclude the administration of the controlled release dosage form be administering to a use environment containing dietary fat. This is evident by the teaching in Cardinal of drugs commonly known to be administered with food such as nifedapine, glipizide, antibiotic and antiviral (ID). Accordingly, the burden of prove is shifted to applicant to show that the use environment taught by the cited prior arts with the present of food, does not have the dietary fat of the claimed invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618